

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1 and 3-12 are pending in the application, with claim 1 being the independent claim. Claims 2 and 13 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. Claims 1-13 stand rejected.

Based on the above amendment and the following remarks, Applicant respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Rejections under 35 U.S.C. § 101***

The Examiner has rejected claim 1 as allegedly unpatentable under 35 U.S.C. § 101. (Paper No. 10, at page 2.) Specifically, the Examiner has stated that "the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process." (Paper No. 10, at page 2.)

Applicant respectfully traverses the rejection. Original claim 1 was directed to a process for the preparation of an AT-III isoform, comprising the step of separating the isoform AT-III $\alpha$  from AT-III $\beta$  on a calcium hydroxyphosphate-based adsorbent. Accordingly, original claim 1 set forth both a process for the preparation of an AT-III isoform and a step in the process comprising separating the isoform AT-III $\alpha$  from AT-III $\beta$  on a calcium hydroxyphosphate-based adsorbent. However, this rejection has been obviated by the foregoing amendment which more clearly sets forth the claimed invention. In an effort to advance prosecution, Applicant has amended claim 1 to

include the steps of providing a solution comprising AT-III $\alpha$  and AT-III $\beta$ , contacting the solution with a calcium hydroxyphosphate-based adsorbent, and eluting an isoform of AT-III. As amended, claim 1 provides more than adequate information to define the steps involved in the process. Thus, Applicants respectfully request that this rejection be withdrawn.

***Rejections under 35 U.S.C. § 112***

The Examiner has rejected claims 1, 2, 4, 6 and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Paper No. 10, at page 2.) Specifically, the Examiner alleges that "[c]laim 1 does not set forth any steps involved in the method/process." (Paper No. 10, at page 2.)

Applicant respectfully disagrees with the Examiner. As discussed above, original claim 1 included such a step, and amended claim 1 provides more than adequate information to define the steps involved in the claimed process.

The Examiner further argued that the term "substantially" in claims 1, 2, 4, 6, and 12 "is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention." (Paper No. 10, at page 3.) As amended, claims 1, 2, 4, 6 and 12 define the process so that one of ordinary skill in the art would recognize the scope of the invention. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

***Rejections under 35 U.S.C. § 102***

Claims 1, 2, 10 and 11 were rejected under 35 U.S.C. 102(b) as being anticipated by Peterson *et al.* (Paper No. 10, at page 3.) Specifically, the Examiner alleged that:

Perterson [*sic*] *et al.* teach the purification [*sic*] AT-III $\alpha$  away from AT-III $\beta$  on a heparin-Sepharose purification column in which the AT-III $\beta$  variant is eluted from the column at higher ionic strength. Peterson *et al.* teach the starting source material for the purification process as the supernatant of centrifuged human plasma the equivalent to Cohn's Fraction I. The human plasma was added to the affinity gel column, and specifically, to a heparin-Sepharose column (see Abstract and Methods section). Thus, the reference anticipates the claimed invention.

(Paper No. 10, at page 3.) Applicant respectfully traverses this rejection.

For a 102(b) rejection to be proper, each and every element of the claims must be found in the cited reference. Peterson *et al.* allegedly teach a method of isolating AT-III $\alpha$  and AT-III $\beta$  on a heparin-Sepharose purification column. (See Abstract and Methods section.) Importantly, Peterson *et al.* do not disclose a process of separating an isoform AT-III $\alpha$  from AT-III $\beta$  comprising a calcium hydroxyphosphate-based adsorbent, as is claimed in the present invention. Because the methods of Peterson *et al.* and the methods of the present application are different, the criteria for anticipation under 35 U.S.C. 102(b) have not been met. Applicant therefore agrees with the Examiner's subsequent statement that "the use of a calcium hydroxyphosphate [*sic*] (or hydroxyapatite) adsorbent column is not expressly taught [by Peterson *et al.*], and there would be no motivation or predictability to of [*sic*] success to separate the isoforms using such a column as set forth in [the] claims [in view of Peterson *et al.*]." (Paper No. 10, at page 4.) Hence, Applicant respectfully requests that the Examiner withdraw this rejection.

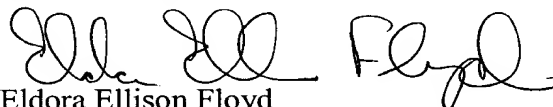
***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read 'Eldora Ellison Floyd', written in a cursive style.

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